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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/981,685	10/17/2001	Frank L. Graham	ADVEC101A-C5A	6575

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EXAMINER

VOGEL, NANCY S

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/981,685

Applicant(s)

GRAHAM ET AL.

Examiner

Nancy Vogel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/21/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: CRF Problem Report.

### **DETAILED ACTION**

This action is in response to applicant's amendment, received 12/16/03. Claims 1-17 are pending in the case.

#### ***Priority***

Applicant's arguments regarding priority at page 5, lines 1-10 of the amendment and remarks, submitted 12/16/03, have been found convincing.

#### ***Drawings***

Applicant's arguments regarding the submission of the Fig. 6B , at page 6, lines 1-13, submitted 12/16/03, have not been found convincing. Note that the application 08/486,549 has not been properly incorporated by reference into the instant application. See Section entitled "Specification" below.

#### ***Sequence Disclosure***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements

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of 37 C.F.R. §§ 1.821-1.825 for the reason(s) set forth on the attached CRF Problem Report. In the most recent submission, the CRF was found to be unreadable, and a replacement CRF is required, along with a statement that the content of the paper and computer readable copy are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

Direct the response to the undersigned. Applicant is requested to return a copy of the CRF Problem Report with the response.

### ***Specification***

The amendment filed 12/16/03 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment to the first paragraph, starting on page 1, line 7 of the specification, i.e. the insertion of "All applications for which priority is claimed are hereby incorporated by reference". This sentence was not present in the specification as originally filed. Note the preliminary amendment filed on 10/17/01 replaced the first paragraph with a paragraph that did not contain this sentence.

Applicant is required to cancel the new matter in the reply to this Office Action.

### ***Claim Rejections - 35 USC § 112***

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/10/03.

Regarding the first basis for rejection, applicant has argued that the term "gene" is defined in the specification as "cDNAs, RNA, or other polynucleotides that encode gene products", and that the amendment to the claims to include the term "expression cassette" clarifies the claims (page 9 of the amendment). However, it is maintained that the amendments to the claims do not eliminate the original basis of the rejection, i.e. it is not clear what, if any, regulatory elements are intended, since "expression cassette" is not clearly defined in terms of what elements are included, i.e. promoter, enhancer, coding region only, etc. Furthermore, if one assumes that the term "expression cassette" includes a promoter for expression of the recited gene, then expression would take place regardless of the control of the recited site-specific recombinase. Therefore, the claims remain vague and indefinite.

Regarding the second basis for rejection, applicant's arguments have been found convincing.

Regarding the third basis for rejection, applicant's arguments have been found convincing.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer et al. (US Patent 4,959,317) in view of Berkner (Curr. Topics Microbiol. Immunol., 158 :39-66, 1992) (both previously cited).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 9/10/03.

In response to this rejection, applicant has argued that Sauer et al. does not overcome unpredictability in the art, i.e. the unpredictability of whether what Sauer discloses for pseudorabies virus would work with adenoviruses. While it is agreed that Sauer et al. do not specifically mention adenoviruses, it is maintained that adenoviruses were well known vectors for the expression of foreign genes, as disclosed by Berkner, and that the statement in Sauer et al. that any virus could be used in the place of pseudorabies virus, provide motivation to combine the references, i.e. to substitute the well known adenovirus, for the exemplified pseudorabies virus. Absolute predictability is not required. Contrary to applicant's arguments, one of ordinary skill in the art would have had a reasonable expectation of success in making this substitution.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nancy Vogel whose telephone number is (571) 272-0780. The examiner can normally be reached on 6:30 - 3:00, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ntv  
3/4/04



**JAMES KETTER**  
**PRIMARY EXAMINER**